April 9, 2002

James A. Deyo, D.V.M., Ph.D., D.A.B.T.
Technical Associate
Eastman Chemical Company
P. O. Box 511
Kingsport, Tennessee 37662

Dear Dr. Deyo:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-pentanone, posted on the ChemRTK HPV Challenge Program Web site on December 3, 2001. I commend Eastman Chemical Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Eastman Chemical Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2 - Pentanone (Methyl Propyl Ketone)

SUMMARY OF EPA COMMENTS

The sponsor, Eastman Chemical Company, submitted a Test Plan and Robust Summaries to EPA for the 2-pentanone (CAS No. 107-87-9; methyl propyl ketone) dated October 12, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on December 3, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. All appropriate SIDS-level tests/estimations have been performed.

2. Health Effects. All appropriate SIDS-level tests have been performed. However, the submitter needs to address deficiencies in the Robust Summaries.

3. Ecological Effects. The submitted ecotoxicity data are adequate and no further testing is required. Additional information is needed to be provided in the acute fish and invertebrate toxicity robust summaries.

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE 2 - PENTANONE (METHYL PROPYL KETONE) CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (Photodegradation, Stability in Water, Biodegradation, Fugacity).

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate test data are available for these endpoints. However, the submitter needs to address a few deficiencies in the robust summaries (see "Specific Comments on Robust Summaries").

Acute Toxicity. Adequate data are available for this endpoint.

Repeated Dose Toxicity. The 10–13-month drinking water study in rats is adequate for this endpoint. The 17.5-week inhalation study is inadequate. However, no further testing is necessary.

Genetic Toxicity (in vitro). Studies on reverse mutation in *Salmonella typhimurium* and *Escherichia coli* and on chromosomal aberrations in Chinese hamster ovary cells are adequate to address the genetic toxicity

endpoints.

Reproductive/Developmental Toxicity. A combined reproductive/developmental inhalation toxicity study in rats is adequate for these endpoints although certain information is missing.

Ecotoxicity (fish, invertebrates, and algae). Adequate data are available for these endpoints. However, additional details are needed in the robust summaries for the acute fish and invertebrate toxicity tests.

Specific Comments on the Robust Summaries

Health Effects.

Reproductive/Developmental Toxicity (inhalation). Although the study is considered adequate, information missing from the robust summary includes: the method for generating the test atmosphere, the timing of exposure days in both sexes in relation to mating and gestation, the timing of final sacrifices with respect to gestation and lactation, and the maternal and paternal endpoints that were analyzed (including the specific organs weighed and examined histologically).

Ecotoxicity. Information missing from the acute fish and invertebrate robust summaries includes: test substance purity, guideline followed, water hardness, and results of analytical monitoring of test concentrations.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.